

## **II. REMARKS AND ARGUMENTS**

### **A. Status of the Claims**

Claims 1, 4-6, and 9-13 are pending. Claims 2-5 and 7-8 have been cancelled without prejudice. Claims 1 and 6 have been amended to include the limitation “bacterial RNAP” previously recited in cancelled claims 2 and 7, respectively. Claims 4-5 and 9-11 have been amended to recite proper antecedent basis for the term “bacterial RNAP”. Support for amended claims 1, 4-6 and 9-11 can be found, for example, in the previous listing of the claims and in the specification as filed. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

### **B. Rejection under 35 U.S.C. § 112**

In the office action, the Examiner maintained her rejection of claims 1 and 3-13 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

In view of the arguments presented during the teleconference of September 1, 2010 and those provided herewith, Applicants respectfully traverse the rejection. The written description requirement of 35 USC 112, first paragraph, is fulfilled when the patent specification described the claimed invention in sufficient detail such that the claim limitations are described so that one skilled in the art would recognize that the applicants had invented the subject matter. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), *In re Herschler*, 591 F.2d 693, 700 (CCPA 1979).

Amended independent claim 1 and amended dependent claim 6 of the present application recite:

Claim 1. A method for identifying an agent that binds to a bacterial RNAP homologous RNA-exit-channel amino-acid sequence in a **bacterial RNAP**, comprising the steps of: (a) preparing a reaction solution including the agent to be tested and a **bacterial RNAP** that contains a bacterial RNAP homologous RNA-exit-channel amino-acid sequence; and (b) detecting at least one of the presence, extent, concentration-dependence, or kinetics of binding of the agent to the homologous bacterial RNAP RNA-exit-channel amino-acid sequence.

Claim 6. The method of claim 1 further comprising the step of: detecting at least one of the presence, extent, concentration-dependence, or kinetics of binding of the agent to a second **bacterial RNAP** that contains a derivative of a bacterial RNAP homologous RNA-exit-channel amino-acid sequence having at least one substitution, insertion, or deletion.

As discussed during the teleconference, the invention of claim 1 is directed to an experiment for identifying agents that bind to a bacterial RNAP homologous RNA-exit-channel amino-acid sequence in a bacterial RNAP. The invention of claim 6 is directed to the experiment of claim 1 with the addition of a control (“detecting at least one of the presence, extent, concentration-dependence, or kinetics of binding of the agent to a second **bacterial RNAP** that contains a derivative of a bacterial RNAP homologous RNA-exit-channel amino-acid sequence having at least one substitution, insertion, or deletion.”).

In the original claims (1 and 6) reference was made to both intact and fragments of bacterial RNAP homologous RNA exit channel amino acid sequence. Claims 1 and 6 have now been amended to include reference to “bacterial RNAP” and not to fragments of RNAP.

Original claims 1 and 6 also made reference to the terms “first entity” and “second entity,” respectively. Claims 1 and 6 have also been amended to replace the term “entity” with “bacterial RNAP.”

With regard to the term “derivative” as recited in amended claim 6, Applicants respectfully submit that this term refers to an altered RNAP that contains an alteration in one specific, well-defined sub-region of the RNAP (i.e., in the RNA-exit-channel homologous amino-acid sequence).

While Applicants maintain the position that at the time of the present invention, as disclosed in the specification, the Applicants were clearly in possession of the invention as applied to *intact RNAP* and *fragments of RNAP* suitable for use as "first entities" (test entities), and as applied to both derivatives of intact RNAP and fragments of RNAP suitable for use as "second identities" (control entities), to further expedite the prosecution of the case, Applicants have amended the claims to delete any reference to *fragments of RNAP*.

In view of the amendment made and arguments presented above and during the September 1, 2010 teleconference, Applicants respectfully submit that proper written description for the pending claims is provided in the present specification. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

**Conclusion**

In view of the Examiner's willingness to issue a non-final office action in the event a notice of allowance is not granted, Applicants have not submitted herewith a Notice of Appeal.

This amendment is being submitted together with a petition for a one-month extension of time and the fee due under 37 C.F.R. 1.17(a)(1). It is believed that no additional fees are due for this submission. However, if it is determined that any additional fees are due or any fee has been overpaid, the Commissioner for Patents is hereby authorized to charge said fee or credit any overpayment to Deposit Account No. 50-0552.

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted  
DAVIDSON, DAVIDSON & KAPPEL, LLC

/Richard V. Zanzalari/

By: \_\_\_\_\_

Richard V. Zanzalari  
Reg. No. 49,032

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940